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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/650,494

08/28/2003

Bradley T. Estes

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06/23/2009

MEDTRONIC

Attn: Noreen Johnson - IP Legal Department

2600 Sofamor Danek Drive

MEMPHIS, TN 38132

EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

06/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/650,494	Applicant(s) ESTES ET AL.	
	Examiner JAMES L. SWIGER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 15, 28-36, 38-44, 46-61, 63-72, 77-88 and 104 is/are pending in the application.
- 4a) Of the above claim(s) 4, 32-34, 47-49, 51-56, 65, 66, 77 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 15, 28-31, 35, 36, 38-44, 46, 50, 57-61, 63, 64, 67-72, 79-88 and 104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/28/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 68 is objected to because of the following informalities: Claims must end with a period. Claim 68 appears to be missing one. Appropriate correction is required.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: In paragraph 27 of the specification, applicant refers to a molded spacer (10) in Fig. 1. This reference numeral seems to be missing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 15, 28-31, 35-36, 38, 42, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Perren et al. (US patent 6,019,793) hereafter "Perren" in view of Shikinami (US Patent 6,281,262) and in view of the following reasoning. Perren discloses an expandable spacer for implantation between opposing endplates of adjacent vertebrae (see Abstract), having a body (1) composed of a shape memory material (see Abstract) that responds to thermal energy while being set into place. Perren discloses an expandable spacer (as shown in Fig. 4 versus Fig. 5), that has vertebral bearing surfaces that define openings (5) in communication with an interior cavity (shown inside, fig. 5, 2) and that is considered at least slightly elongated. It is noted that when Perren is first inserted into the spine it has a first size and a first configuration. A peripheral sidewall in this first configuration also has a first lateral dimension and the vertebral surfaces that the implant would be in contact with would also define a first bearing surface area. When responding to thermal energy (heat, Col. 1, lines 30-40) Perren teaches that the implant expands to a second configuration (such as shown in Fig. 5). In light of this a second portion of the vertebral endplate would then be available with a peripheral sidewall and would also be in a second configuration with a second lateral dimension. In comparing these two situations, it is noted that it is an obvious modification of Perren, that the expandable spacer has bearing surfaces areas of different sizes. In other words, if a spacer implant is inserted with one size and then is permitted to expand by some means (in this case heat), it would have a second configuration that is larger than the first. Also along these lines, a spacer would be fully

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capable of contacting larger areas of the vertebral surface in between the two configurations, as the larger implant would cover a larger surface area and be fully capable of covering other areas of the vertebra such as in a cervical vertebra compared to only a smaller portion of the vertebra. It is noted that Perren further teaches the step including "allowing the spacing device to reach the transition temperature and a predetermined configuration suitable to its spacing function," (Col. 1, lines 55-65). Thus in the spirit of the invention, this device can be inserted having a smaller profile, where it can then be influenced to have a second configuration.

Perren discloses the claimed invention except where the material that expands is made of a polymeric material such as polylactide. Shikinami discloses polymeric shape-memory material that can have another shape at a higher temperature (for example, Col. 5, lines 31-50) that is useful in surgical applications (see also Co. 2, lines 28-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Perren having at least the polymeric shape-memory material of Shikinami to permit further biocompatibility and function in use as a spinal implant.

Claims 2, 43-44, 50 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren in view of Shikinami as applied to claims 28 and 42 respectively above, and further in view of Sanders et al. (US patent 5,290,289) hereafter Sanders. Perren in view of Shikinami disclose the claimed invention except for specific shapes of the spacers, compressed or flattened shapes, cylindrical shapes, or varying cross sections taken at different points. Sanders discloses a memory material structure

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shown in Fig. 6 that is used to cause the invention (in the reference, a rod) to better fit to the surgical application. It has a varying shape (along 36) compared to Fig. 7, where is a circle or in a spiraled shape, as well as having a tapered end where it overlaps that creates a varying cross section in the structure. Since varying shapes or sizes may be used in the invention depending on the surgical application at hand, different configurations may be used. In light of this, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Perren in view of Shikinami having at least multiple shape characteristics of Sanders to permit size and shape variations that will give the surgeon more options depending on the application.

Claims 39-41, 59-61, 63-64, 67, 70, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren in view of Shikinami as applied to claim 38 and 42 above, and further in view of Ferree (US Patent 6,491,724). Perren in view of Shikinami discloses the claimed invention except for the use of osteogenic material in the internal cavity, wherein the osteogenic material is selected from the group consisting of: a bone morphogenic protein, a recombinant bone morphogenic protein, demineralized bone matrix, and mixtures thereof. Ferree discloses an expandable spacer and teaches the use of osteogenic material in the internal cavity for the promotion of bone growth (Col. 2, lines 2-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Perren in view of Shikinami having at least the osteogenic material in further view of Ferree to promote bone growth after the spacer of varying size is implanted.

Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren in view of Shikinami. Perren in view of Shikinami disclose the claimed invention except for a body having a specific compressive modulus such as between 2 MPa and 30 MPa. However it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spacer having the ability to have a specific compressive modulus, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 80-85 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren in view of Shikinami. Perren in view of Shikinami disclose the claimed invention except for having multiple expandable spacers having additional secondary or tertiary configurations compared to those of another, or first spacer or having materials varying throughout. With regards to this, use of an additional or a second spacer having it's own expanded conditions or specific materials would be obvious to one having ordinary skill in the art at the time the invention was made since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spacer having varied material throughout since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 68-69 and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perren in view of Shikinami as applied to claim 38 and 42 above, and further in view of Ferree. Perren in view of Shikinami as applied to claim 38 and 42 above, and further in view of Ferree disclose the claimed invention except for body having a specific compressive modulus such as between 2 MPa and 30 MPa. However it is noted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spacer having the ability to have a specific compressive modulus, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments, see arguments, filed 3/11/2009, with respect to claims 2-3, 15, 28-31, 35-36, 38-44, 46, 50, 57-61, 63-64, 67-72, 79-88, 104 have been fully considered and are persuasive. The rejection of the above claims has been withdrawn.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775